

REMARKS

Status of the Claims

Claims 1 and 4-10 are currently pending in the application. Claims 1-19 stand rejected. Claims 1 and 4-10 have been amended. Claims 2, 3 and 11-19 have been cancelled. All amendments and cancellations are made without prejudice or disclaimer. No new matter has been added by way of the present amendments. Specifically, the amendment to claim 1 is supported by the specification at, for instance, page 16, lines 11-20, and page 26, lines 20-21. Amendments of claims 4 and 5 are to conform the claims more closely to US practice. Other amendments of claims 6-10 are merely clarifying amendments which do not limit the scope of the claims. Reconsideration is respectfully requested.

Interview

Applicants and Applicants' representatives thank the Examiner for extending the courtesy of an interview on April 21, 2008. The substance of the interview is substantially as reflected in the Interview Summary to be made of record. Briefly, during the interview, indefiniteness issues barring allowance of the present claims were discussed. Particularly, a proposed amendment to claim 1 and the specification at the paragraph beginning at page 16, line 11 were reviewed by the Examiner and discussed. The Examiner indicated agreement that if the proposed amendments, with some minor changes suggested by the Examiner, to claim 1 and the specification were submitted, they would be acceptable and most likely address at least the rejections under 35 U.S.C. § 112, second paragraph, and perhaps the rejections under 35 U.S.C. § 112, first

paragraph. Therefore, Applicants submit herein the proposed claim amendments, as suggested by the Examiner, for entry into the record and consideration.

Rejections Under 35 U.S.C. § 112, First Paragraph

Written Description

Claims 1-19 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. (See, Office Action of January 22, 2008, at pages 2-3, hereinafter, “Office Action”). Claims 2, 3 and 11-19 have been cancelled herein without prejudice or disclaimer, thereby obviating the rejection of these claims. Applicants traverse the rejection as to the remaining claims as follows.

The Examiner states that there is insufficient disclosure in the specification to adequately support a claim encompassing all known hydrolase enzymes. The Examiner believes that each hydrolase enzyme is different and the activity of every hydrolase cannot be predicted based on the disclosure of only two species of hydrolases.

Although Applicants do not agree that the present claims lack written description support, particularly since one of skill knows how to isolate a lipase enzyme and how to characterize its activity, to expedite prosecution, claim 1 has been amended herein to recite, in part, “in the presence of a *Candida Antarctica* lipase ...” Thus, the claims, at least as amended, do not encompass “a multitude of hydrolases neither contemplated nor disclosed.” The claims include a hydrolase specifically from *Candida Antarctica*. Support for this amendment may be found in the specification at, for instance, page 26, lines 20-21.

Since no specific reasoning is provided for the rejection of dependent claims 4-10, dependent claims 4-10 are believed to be adequately supported by the specification as, *inter alia*, depending from an adequately supported base claim, amended claim 1.

Reconsideration and withdrawal of the written description rejection of claims 1 and 4-10 are respectfully requested.

Enablement

Claims 1-19 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. (*See*, Office Action, at pages 4-6). Claims 2, 3 and 11-19 have been cancelled herein without prejudice or disclaimer, thereby obviating the rejection of these claims. Applicants traverse the rejection as to the remaining claims as follows.

The Examiner's comments basically follow those provided above regarding the written description-based rejection. The Examiner states that the specification does not disclose "other hydrolases that are capable of carrying out the claimed reaction nor a method that does not require undue experimentation to select other stereoselective hydrolases." (*Id.* at page 4).

Again, although Applicants do not agree that the present claims lack enablement support, for the reasons provided of record and stated above, to expedite prosecution, claim 1 has been amended herein to recite, in part, "in the presence of a *Candida Antarctica* lipase ..." Thus, the claims, at least as amended, do not encompass "a multitude of hydrolases neither contemplated nor disclosed." The claims include a hydrolase specifically from *Candida Antarctica*. Support for this amendment may be found in the specification at, for instance, page 26, lines 20-21.

Since no specific reasoning is provided for the rejection of dependent claims 4-10, dependent claims 4-10 are believed to be enabled for, *inter alia*, depending from an enabled base claim, amended claim 1.

Reconsideration and withdrawal of the enablement rejection of claims 1 and 4-10 are respectfully requested.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-19 stand rejected under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. (See, Office Action, at pages 6-7). Claims 2, 3 and 11-19 have been cancelled herein without prejudice or disclaimer, thereby obviating the rejection of these claims. Applicants traverse the rejection as to the remaining claims as follows.

The Examiner states that since claim 1 is drawn to N-substituted β -amino acid alkyl esters or N-substituted 2-homopipeolic acid esters, and since there is no mention of rings in this beginning section of the claim, the recitation of rings later in the claim lacks antecedent basis. The Examiner additionally states that claim 1 is rejected because it is unclear how R¹ and R² may be bonded when R² is hydrogen. The Examiner also states that claims 1 and 6-10 are indefinite for reciting the phrase “represented by the formula.” The Examiner states that the term “represented” is not defined by the specification. Finally, the Examiner states that claims 6-10 are vague for reciting the phrase “wherein Ar, R¹, R², R³, R⁴ and R⁵ have the same meaning as defined above.”

Applicants address each of these concerns, in order, as follows. Present claim 1 recites, in part, “A process for preparing an optically active β-amino acid and an optically active β-amino acid ester or N-substituted 2-homopipeolic acid and an optically active N-substituted 2-homopipeolic acid ester . . .” However, pipeolic acid is a 6-membered ring. (See, formula (1-b) on page 5, line 10 of the present application). Therefore, it is believed that sufficient antecedent basis exists for groups comprising ring structures in the claims. Furthermore, there is ample support in the specification for the presence of a 6-membered ring in the presently claimed compounds and compositions.

The issue concerning formation of a ring when R² is defined as only a hydrogen atom is believed to have been addressed by the additional amendment of claim 1, and dependent claims, to include an alternative embodiment wherein R¹ and R² together, with the atoms to which they are bonded, form a 6-membered ring. Applicants believe that ample support exists for this alternative at least at page 16, lines 11-20 of the present specification. Discussion of this amendment during the Interview of April 21, 2008 is believed to have resulted in agreement that the presently submitted amendments adequately address this issue.

The Examiner’s requirement that the claims recite “is” instead of “represented by” seems unusual in that there is no support for the Examiner’s alternative interpretation of this term anywhere in the history of patents, the Rules, the Laws or legal precedent. It is respectfully pointed out that the term “represented by” is recited in the allowed claims of literally thousands (exactly 28,110 as of the time of this paper) of granted US patents. Unless the Examiner is prepared to state on the record that all of these thousands of issued patents with the term

“represented by” in the claims are presently invalid for being vague or indefinite, Applicants do not feel there is any basis to require amendment of the claims as proposed by the Examiner.

Phrases such as, “wherein År, R¹, R², R³, R⁴ and R⁵ have the same meaning as defined above” have been removed from all of the pending claims. The claims have been further amended to reiterate the definitions of the recited variables according to those provided in claim 1, as amended.

Therefore, reconsideration and withdrawal of the indefiniteness rejection of claims 1 and 4-10 are respectfully requested.

Application No. 10/510,483
Amendment dated April 22, 2008
Reply to Office Action of January 22, 2008

Docket No.: 0283-0200PUS1

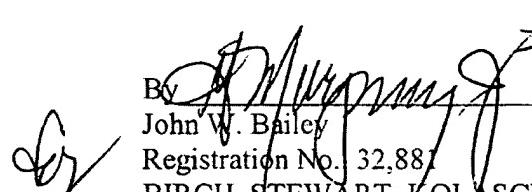
CONCLUSION

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: April 22, 2008

Respectfully submitted,

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